

Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were completed in June 2016.

Original Approvals

This section displays the original approval. To read the complete approval, please refer to 21 CFR Parts 500 and the related Federal Register notices.

ANADA Number: 200-587

Trade Name: FerroForte™
Pioneer: Gleptosil®
Ingredients: Gleptoferron
Sponsor: Cross Vetpharm Group Ltd.
Approval Date: June 20, 2016
Status: OTC
Route: Intramuscular injection
Species: Swine (baby pigs)
Drug Form: Solution
Concentration: 200 mg iron/mL
Indications: For the prevention of Baby Pig Anemia due to iron deficiency, and for the treatment of Baby Pig Anemia due to iron deficiency.

Sponsor Change

NADA Numbers: 092-709, 092-710

Previous Sponsor: ConAgra Pet Products Co.
New Sponsor: Sergeant's Pet Care Products Inc.
Drug Labeler Code: 21091

Sponsor Address Change

Sponsor: Alexion Pharmaceuticals, Inc.
Previous: 33 Hayden Ave, Lexington, MA 02421
New Address: 100 College St New Haven, CT 06510

Withdrawal of Approval

NADA Number: 007-076

Sponsor: Cross Vetpharm Group Ltd.
Trade Name: Sulfa-Nox Liquid
Ingredients: Sulfaquinoxaline

This product is withdrawn because the product is no longer manufactured or marketed.

21 CFR 520.2325a

NADA Number: 008-244

Sponsor: Cross Vetpharm Group Ltd.
Trade Name: Sulfa-Nox Concentrate
Ingredients: Sulfaquinoxaline

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21 CFR 520.2325a

NADA Number: 041–955

Sponsor: Cross Vetpharm Group Ltd.
Trade Name: Erythromycin Medicated Premix
Ingredients: Erythromycin thiocyanate

This product is withdrawn because the product is no longer manufactured or marketed.

21 CFR 558.248

NADA Number: 049–729

Sponsor: Cross Vetpharm Group Ltd.
Trade Name: Purina® Sulfa
Ingredients: Sulfamethazine

This product is withdrawn because the product is no longer manufactured or marketed.

21 CFR 522.2260a

NADA Number: 100–128

Sponsor: Cross Vetpharm Group Ltd.
Trade Name: Supersweet Medipak Tylan® 10
Ingredients: Tylosin phosphate

This product is withdrawn because the product is no longer manufactured or marketed.

21 CFR 558.625

ANADA Number: 200–307

Sponsor: Vetoquinol N.-A., Inc.
Trade Name: Penicillin G Potassium, USP
Ingredients: Penicillin G Potassium

This product is withdrawn because the product is no longer manufactured or marketed.

21 CFR 520.1696b

Suitability Petitions

Number: 16-P-1169

Petitioner: e5 Pharma, LLC.
Date Filed: April 13, 2016
Action: Denied
Action Date: June 8, 2016
Description: The petitioner requests to file an ANADA for a generic methimazole tablet that differs from the pioneer product, FELIMAZOLE, sponsored by Dechra, Ltd under NADA 141-292. The proposed change is in dosage form. The RLNAD is approved as a coated tablet. The proposed change is for a rapidly disintegrating tablet.